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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,871	08/29/2003	Horace Winston Hale	HORA.P0101US	9347

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EXAMINER

REIMERS, ANNETTE R

ART UNIT PAPER NUMBER

3733

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/651,871	<b>Applicant(s)</b> HALE ET AL.	
	<b>Examiner</b> Annette R. Reimers	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006 and 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 41-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2003 and 09 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Interview Summary**

Examiner stated in the interview summary, dated May 15, 2006, that she would contact applicant's representative, Mr. Mark Johnson, prior to sending out an additional office action. Examiner contacted Mr. Johnson and stated in a message to Mr. Johnson that an additional non-final office action would be administered for this case. It is noted that the means for language disclosed in new claims 41-58 incorporates the use of structure. As such, these claims will not be interpreted using 112 6<sup>th</sup> paragraph standards.

### ***Specification***

The abstract of the disclosure is objected to because implied language is used, i.e. "the present invention." Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-46, 52 and 58 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 41, lines 6-7, claim 52, lines 1-3, and claim 48, lines 1-3, applicant positively recites part of a human, i.e. "means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet." Thus, claims 41-46, 52 and 58 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-2, 4-6, 8-11, 14-17, 19-20, 41-44, 46-49, 51-55, 57-58 are rejected under 35 U.S.C. 102(e) as being anticipated by the Soboleski et al. (US Patent Publication Number 2002/0151895).

Soboleski et al. disclose a facet implant comprising a superior implant, 14, having an articulating surface and a fixation surface and configured for placement on a superior articular facet, a inferior implant, 16, having an articulating surface and a fixation surface and configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism, wherein the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact, and a translaminar fixation mechanism, at 19, for securing the inferior implant to the inferior articular facet (see figures 2 and 3A-3F and paragraph 0043). The superior implant and the inferior implant comprise a surface fixation mechanism, e.g. 54, 64, 68, 72, 74, 84 or 88 such as one or more pegs, one or more pips, ridges, or one or more screws (see figure 3A-3F paragraphs 0049-0052). Furthermore, Soboleski et al. teach the use of a an implant composed of at least one of cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, and Ti/Al/V (see paragraph 0048).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Soboleski et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under

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attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soboleski et al. (US Patent Publication Number 2002/0151895).

Soboleski et al. disclose the claimed invention except for the inferior implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Soboleski et al. with the inferior implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only

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routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Soboleski et al. teach that the implants can be of various shapes and sizes (see paragraphs 0045-0047).

Claims 7, 18, 45, 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soboleski et al. (US Patent Publication Number 2002/0151895) in view of Yuan et al. (US Patent Publication Number 2005/0143818).

Soboleski et al. disclose the claimed invention except for the fixation surfaces having a porous coating. Yuan et al. disclose a facet implant and teach a fixation surface having a porous coating in order to promote bone ingrowth and fixation (see paragraph 0096). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Soboleski et al. with the fixation surfaces having a porous coating, in view of Yuan et al., in order to promote bone ingrowth and fixation.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER